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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,747 08/25/98 TOROSSIAN

F TORO-0101-PU

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HM12/0828

EXAMINER

SHAHNAN-SHAH, K

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/125,747

Applicant(s)

TOROSSIAN, FERNAND NARBEBY

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the time or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2001 and 30 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2f.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 22.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The Examiner of U.S. Patent application SN 09/125,757 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Shahnan-Shah, Technology Center 1600, Art Unit 1645.
2. The request filed on May 30, 2001, paper # 19 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/125,747 is acceptable and a CPA has been established. An action on the CPA follows.
3. Supplemental Amendment received May 30, 2001 paper # 20 is acknowledged.
4. Supplemental Information Disclosure received May 30, 2001 paper # 21 is acknowledged.
5. Amendment D after final received on 4/26/2001 was not entered based on CPA transmittal form received 5/30/2001. Box 1 was not marked on the form. Also supplemental amendment received 5/30/2001 did not ask for the entry of the amended claims. After a telephonic interview with the applicant's attorney on August 17, 2001 amendment D (claims 9-16) has been entered and claims are under consideration. (see summary interview report , paper # 22).

Supplemental Information Disclosure Statement

6. Acknowledgment made on correction of the typographical error in the citation. And the addition of the proper serial number for the reference (08/347,322) has been noted.

Objection(s) Withdrawn

7. The objection to the abstract made in paragraph 7 of the office action mailed 11/ 21/ 2000 (paper # 15) is withdrawn in light of applicant's Abstract submitted to the June 21, 2000 amendment.
8. The objection to claim 15 made in paragraph 16 of the office action mailed 11/ 21/ 2000

(paper # 15) is withdrawn in light of applicant's amendment D, received on 4/26/2001.

Objection(s) Moot

9. The objection to a portion of claim 15 made in paragraph 16 of the office action mailed 11/ 21/ 2000 (paper # 15) is moot in light of applicant's cancellation of that portion of the claim in amendment D, received on 4/26/2001.

Rejection(s) Withdrawn

Claim Rejections - 35 USC § 112, Second Paragraph

10. The rejection to claims 9-16 made in paragraph 15 of the office action mailed 11/ 21/ 2000 (paper # 15) under 35 USC § 112, Second Paragraph is withdrawn in light of applicant's amendment D, received on 4/26/2001.

Rejection(s) Maintained

Claim Rejections - 35 USC § 112, First Paragraph

11. The rejection to claims 9-16 made in paragraph 15 of the office action mailed 11/ 21/ 2000 (paper # 15) under 35 USC § 112, First Paragraph is maintained.

The specification still fails to set forth sufficient evidence showing that the claimed vaccine complex could be made and/or used with "dual molecules" of part (a) of amended claim 9 comprising a "functional amino acid arm" and a "genetic ribonucleic acid arm". No guidance has been provided as to their source and as to how they are produced.

Claim 12, which depends from claim 9, 10 or 11, recites the immunomodulatory and vaccine complex of the instant invention for use in the treatment of diseases caused by *Helicobacter* bacteria "by the production of antibodies". However, the specification on page 3,

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lines 3 and 4, states the “inefficacy” of the *Helicobacter*-specific antibodies in protecting an individual.

The specification does not enable a vaccine comprising the components recited in part (a) of claim 9. Instant specification does not provide a clear written description of “a functional amino acid arm, ensuring binding to a target, with a genetic RNA arm corresponding to the coded description of the composition of the functional arm” (claim 9). Whether or not these components are of bacterial or non-bacterial origin is not disclosed.

Furthermore, page 13 of the specification recites collagen type III as the “immunity adjuvant factor”, and the complex as containing “amino acid sequences” of the collagen type III. However, claim 11 recites that the amino acids from collagen are selected from the various amino acids recited in the claim. The collagen type III is stated on page 13 to be characterized by “Amino acid sequences similar to” the “sequence” shown on page 13, wherein several individual amino acid residues are recited one below the other. No amino acid sequences are provided or identified specifically by a SEQ ID number. It is unclear what Applicant means by amino acid “sequences” are similar to the individual amino acids (not sequences) recited on page 13. With this description, one of ordinary skill in the art would not be able to understand whether the whole sequence is present in the complex, or any one of the recited amino acids is included in the complex, or a mixture of any of these amino acids is included in the complex, and therefore would not be able to make and/or use and/or reproducibly practice the invention without undue experimentation.

Further, the specification does not allow one of ordinary skill in the art to grasp the nature of the association between the multiple components present in the “complex”. For example, the

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optimal amounts or proportions of different "bacterial membrane fractions", i.e., glycopeptides and/or lipopolysaccharides and the ribonucleic acid arm, that should be present in the complex such that the complex can accomplish its alleged therapeutic and/or preventive functions are not disclosed.

In summary, the actual invention is not described in such a way that one skilled in the art could grasp the invention and make and/or use the invention and/or reproducibly practice the invention with a reasonable expectation of success, without undue experimentation. The breadth of instant claims is not commensurate in scope with the enabling disclosure or evidence. In the absence of specific guidance and evidence, instant claims are viewed as not meeting the enablement provisions of 35 U.S.C. § 112, first paragraph.

Applicant's Arguments & Office Action Response

12. Applicant contends in amended D that these amendments have been made in order to overcome all of the Examiner's rejections and objections to the subject matter of claims 9-16 as originally presented and is sufficient to put all the claims in proper form for allowance. (see page 4, remarks of amendment D filed 4/26/2001). However for the reasons given in paragraph 11 of this office action the specification still fails to enable and set forth sufficient evidence showing that the claimed vaccine complex could be made and used by one of ordinary skill in the art without undue experimentation.

Conclusion

13. Claims 9-16 stand rejected.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnian-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 8/24/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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MARK NAVARRO
PRIMARY EXAMINER